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| PRE-APPEAL BRIEF REQUEST FOR REVIEW   |                      |                          |                 |
|   |                      | 206-024                  |                 |
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| Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  |                      |                          |                 |
| on  | First Named Inventor |                          |                 |
| Signature S & W   | SHANKS, Staven C.    |                          |                 |
| 24 .  | Art Unit Examiner    |                          |                 |
| Typed or printed Sandra L. Etherton   | 3739                 | 7 140                    | enry M. Johnson |
| latest  |                      |                          |                 |
| Applicant requests review of the first rejection in the above-identified application. No amendments are being filed   |                      |                          |                 |
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED CENTRAL FAX CENTER

OCT 0 2 2007

In re Application of

Applicants:

SHANKS, Steven C. et al.

Title of Invention:

Laser Device to Treat Sympathetic and Parasympathetic Nervous System

Filed:

02/04/2004

Serial Number:

10/772,973

Atty Docket No.:

206-024

Mail Stop AF Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

# STATEMENT ACCOMPANYING THE REQUEST FOR PRE-APPEAL BRIEF REVIEW

This statement is in support of Applicants' request for a Pre-Appeal Brief Review according to the USPTO Official Gazette Notices of July 12, 2005 establishing a Pre-Appeal Brief Conference Pilot Program, later indefinitely extended by the USPTO Official Gazette Notices of February 7, 2006. This statement is being submitted along with a Notice of Appeal and a Pre-Appeal Brief Request for Review. Applicants are entitled to file an Appeal according to 35 U.S.C. §134 because their claims have been twice rejected.

#### I. Prosecution History

Applicants filed this application on February 4, 2004. There have been six office actions on the merits, three of which have been deemed "final." There are currently eight claims still pending: claims 4, 10, and 14-19.

In the Examiner's office action dated January 16, 2007, he rejected claims 4, 10, and 14-19 as obvious in light of U.S. Patent No. 6,582,454 to Yayama ("Yayama") in view of U.S. Patent No. 6,267,779 to Gerdes ("Gerdes"). Applicants amended the claims to point out that the beam spots of their therapeutic laser beams do not intersect on the patient. Applicants further explained that Yayama and Gerdes teach away from

non-intersecting laser beams. The Examiner rejected the amendments and simply stated that the wands of Gerdes were capable of producing non-intersecting beams.

Applicants next filed a Request for Continuing Examination including the same amendments and again explaining that Yayama and Gerdes teach away from non-intersecting laser beams. The Examiner responded with the office action dated July 2, 2007. In his response, the Examiner erroneously finds that Yayama teaches non-intersecting beams.

Applicants are now filing an appeal and requesting a pre-appeal brief review because the Examiner clearly erred in finding that Yayama teaches non-intersecting beams, an element required by each of Applicants' remaining claims. Applicants assert that Yayama affirmatively teaches multiple intersecting beams and teaches away from multiple non-intersecting beams. Additionally, Applicants assert that Gerdes affirmatively teaches away from multiple non-intersecting beams as well. Because neither Gerdes nor Yayama teaches laser beams that provide therapeutic benefits without intersecting, the Examiner has failed to establish a *prima facie* case of obviousness.

#### II. Argument

The Examiner has rejected claims 4, 10, and 14-19 under 35 USC 103(a) as being unpatentable over Yayama in view of Gerdes. A claim is prima facie obvious only if the prior art reference (or references when combined) teach or suggest all the claim limitations. MPEP §2143. Moreover, a prior art reference must be considered in its entirety, including portions that would teach away from the claimed invention. MPEP §2141.02; W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Finally, it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. MPEP §2145; see also KSR Int'l Co. v. Teleflex Inc., 550 U.S. \_\_\_\_\_\_, 12 (2007) (explaining that if prior art that teaches away from the claimed combination, the claimed combination is more likely to be nonobvious).

Independent claims 4 and 10 contain the limitation that multiple color laser beams do not intersect. The Examiner has clearly erred in finding that Yayama teaches non-intersecting beams. Rather, Yayama and Gerdes both fail to teach or suggest this

claim limitation. Moreover, Yayama and Gerdes teach away from using multiple laser beams that do not intersect.

#### The Examiner erroneously concluded that Yayama teaches nonintersection beams.

The Examiner asserts in his most recent office action that Figure 3 of Yayama teaches non-intersecting beams. The Examiner has clearly erred in his reading of Yayama and understanding of Figure 3. It is clear from both Figure 3 and the overall description of the invention that the beams taught by Yayama are intended to intersect and do intersect.

Figure 3 of Yayama shows a change in projection range by changing optical systems 31, 32, and 33. In order for the multiple laser beams to be non-intersecting, they would have to be parallel beams or divergent beams. Nothing in Figure 3 or Yayama's disclosure teaches or even suggests parallel or divergent beams. For example, as explained in Yayama in reference to Figure 3, "[t]he projecting part 3 is equipped with optical systems 31, 32 and 33, which respectively condense the blue, green and red laser beams at the same point." Yayama, col. 4, lines 17-22 (emphasis added). This explanation is repeated throughout Yayama's disclosure. See, e.g., Yayama, col. 4, lines 2-5 ("The projecting part 3 condenses the laser beams of blue, green and red emitted by the laser beam generating part 1 on the treatment object region 500 so that the condensed laser beams are projected onto the treatment object region 500."); Yayama, col. 4, lines 33-36 ("The blue, green and red laser beams are condensed and projected onto the treatment target region 500 due to the function of the optical systems 31, 32 and 33 of the projecting part 3, respectively.").

Accordingly, the Examiner clearly erred in reading Figure 3 as showing non-intersecting beams. Yayama only teaches and suggests intersecting, or condensed, beams. Because the Examiner erroneously relies on Yayama to establish an element of Applicants' claims, multiple non-intersecting beams, the Examiner has failed to establish a prima facie case of obviousness.

## Yayama teaches away from using multiple laser beams that do not intersect.

Condensing the multiple laser beams into a single beam that acts on one location of a patient is critical to Yayama's invention. As explained in Yayama's disclosure, "the laser beams of blue, green and red act on the treatment object region 500 and collaborate thereon with one another so that the treatment effects can be improved." Yayama, col. 4, lines 50-53; see also Yayama, col. 2, lines 31-34 ("[T]he laser beams of the different colors related to different physiological actions collaborate with each other, so that the effects brought by LLT can be enhanced.").

Please refer to page 6 of Applicants' May 16, 2007 Request for Continuing Examination for a more detailed explanation of how Yayama fails to teach or suggest laser beams that do not intersect and for an explanation of how Yayama actually teaches away from non-intersecting beams.

## Gerdes teaches away from using multiple laser beams that do not intersect.

Gerdes also fails to teach or suggest laser beams that do not intersect and instead teaches away from non-intersecting laser beams. According to Gerdes' disclosure, "the method of treatment of the present invention involves the exposure of the tissue to a plurality of converging beams of infrared radiation." Gerdes, col. 12, lines 57-59; see also Gerdes, Fig. 7 (illustrating how the laser beams should converge). Moreover, Gerdes specifically requires the laser beams to intersect because "[t]he intersection of the emitted . . . laser radiation significantly improves the absorption of the energy by the tissue at and proximate to the region or point of intersection "B" of the beams 127, 132." Gerdes, col. 13, lines 6-9. Gerdes discloses multiple handheld lasers "whereby the beams of infrared treatment lasers intersect" and a positioning device for maintaining laser wands so that the "therapeutic laser beams hav[e] an intersection region." Gerdes, Abstract; Gerdes, col. 12, lines 64-67; Gerdes, col. 13, lines 29-31.

Please refer to pages 7-8 of Applicants' May 16, 2007 Request for Continuing Examination for a more detailed explanation of how Gerdes fails to teach or suggest

laser beams that do not intersect and for an explanation of how Gerdes actually teaches away from non-intersecting beams.

# 4. Yayama and Gerdes fall to render Applicants' claimed invention obvious.

Because the combination of Yayama and Gerdes teach away from non-intersecting multiple colored laser beams, because neither Gerdes nor Yayama independently teaches or suggests multiple laser beams that do not intersect, and because Gerdes and Yayama actually teach away from non-intersecting laser beams, Gerdes and Yayama fail to disclose a claim limitation found in each of Applicants' independent claims 4 and 10. Because claims 14-19 depend from claim 10, Gerdes and Yayama also fail to disclose a claim limitation of claims 14-19. Accordingly, no prima facie case of obviousness has been established with respect to Applicants' remaining claims.

#### III. Conclusion

Applicants respectfully submit (1) that the Examiner clearly erred in finding that Yayama teaches multiple non-intersecting laser beams and (2) that a prima facie case of obviousness has not been established. Applicants respectfully request that the application be allowed to proceed to issuance.

Respectfully submitted,

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